

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

CIVIL ACTION NUMBER:

1:19-md-02875-RBK-KW

**DISCOVERY MOTION HEARING
(Via Zoom videoconference)
REDACTED COPY**

Monday, September 13, 2021
Commencing at 10:13 a.m.

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Proceedings recorded by mechanical stenography;
transcript produced by computer-aided transcription.

1 (ALL PARTIES VIA ZOOM VIDEOCONFERENCE; MONDAY,
2 SEPTEMBER 13, 2021; 10:13 A.M.)

3 THE COURT: We had technical difficulties and we're
4 ready to proceed. I'll ask you to mute your mic when you're
5 not speaking, and otherwise, we're ready to go.

6 Brian, will you be addressing this first on behalf of
7 the Teva defendants?

8 MR. RUBENSTEIN: Yes, Your Honor.

9 THE COURT: All right.

10 MR. RUBENSTEIN: Thank you, good morning, Your Honor.
11 Again, Brian Rubenstein for the Teva defendants. And I guess
12 before we dive into the documents, I'm not exactly sure how
13 Your Honor wants to approach this hearing this morning.

14 I just wanted to address some overarching issues that
15 need to be thought about when considering why these documents
16 should remain confidential.

17 THE COURT: That's fine. Let me just interrupt you
18 for a second. I appreciate receiving that information first,
19 and then what I intend to do is go document by document. All
20 right? Or at least category by category.

21 MR. RUBENSTEIN: Okay. Like I said, there's just a
22 few overarching issues that I wanted to address first and the
23 first thing is, you know, this is a pretty unique situation.
24 You know, the codefendants in this litigation are also Teva's
25 direct competitors and that should weigh heavily in favor of

1 keeping these documents marked as confidential.

2 The plaintiffs -- the cases that the plaintiffs
3 cited, none of them had a situation where they were direct
4 competitors as codefendants or otherwise involved in the
5 litigation.

6 Second, there's nothing in here that Teva has marked
7 as confidential because it's embarrassing. Teva is simply
8 trying to protect its legitimate business interests by keeping
9 confidential some of its most sensitive information and
10 thought processes from the codefendants who are its direct
11 competitors.

12 Third, the nature of the pharmaceutical industry and
13 the generic pharmaceutical industry, in particular, is highly
14 competitive and not just on price. It's highly competitive on
15 processes, formulations and internal strategies, all of which
16 are implicated by the documents the plaintiffs are challenging
17 here.

18 Fourth, the discovery of the nitrosamine impurities
19 is a very new issue in the pharmaceutical industry. It is
20 evolving every day and every single company in the industry is
21 involved and affected, not just the companies in this
22 litigation. How each company is tackling this issue is highly
23 sensitive and proprietary, and many of the documents that the
24 plaintiffs are trying to dedesignate show Teva's internal
25 proprietary processes for tackling this very new issue.

1 And last, one of plaintiffs' primary arguments for
2 dedesignating these documents is that they're old, but there's
3 no bright line rule for dedesignating documents based on age,
4 and the plaintiffs do not cite to one.

5 Going back to current run, Teva's internal processes
6 in dedesignating a document simply based on its age would
7 create a very slippery slope in this litigation, for all of
8 these aforementioned factors apply.

9 Now, in the plaintiffs' letter brief, they cite to a
10 couple cases but what they don't cite to is to the protective
11 order entered into the case itself. And this protective order
12 was heavily negotiated among the parties.

13 And the term "confidential information" is defined as
14 information that is proprietary, trade secret and are highly
15 sensitive -- sorry, commercial information which is believed
16 in good faith by the producing party to have the potential, if
17 disclosed, for causing competitive harm to it or giving a
18 competitive advantage to others.

19 Importantly, it's producing parties' reasonable good
20 faith that is the benchmark for these standards. And the
21 plaintiffs also ignore the ruling that Your Honor has
22 previously made in this case, in ZHP's motion to seal certain
23 documents, that the privacy interest of third parties and the
24 producing parties' representation that disclosure would harm
25 its relationship with the third party suffice to overcome the

1 presumption of public access.

2 And it's stated in the affidavit of Tony Binsol,
3 Teva's Senior Director of Global Quality Management Systems,
4 many of the documents at issue here would directly impact
5 Teva's relationship with these third parties. Teva has
6 complex ongoing relationships with many companies around the
7 world, including numerous parties in this litigation, and
8 publication of these documents could hurt those business
9 interests globally.

10 You cannot look at this case in a vacuum. This is
11 not just about whether Teva still sells Valsartan in the
12 United States or whether it still buys Valsartan API from ZHP
13 and Mylan. Teva conducts business with all of these
14 codefendants and the business relationships are not defined by
15 the scope of this litigation.

16 Now, as we said in our letter brief, our documents
17 basically fall into one of six categories: Formulation for
18 finished dose of Valsartan and API, a purchase order,
19 development of test methods and testing strategies for
20 nitrosamine impurities, audit reports and related
21 communications to those audit reports, internal risk
22 assessments and calculations for health hazard assessment.

23 So that's pretty much all I wanted to say before
24 delving into the documents. However Your Honor would like to
25 proceed, it's fine with me.

1 THE COURT: All right. Thank you very much.

2 Mr. Stanoch?

3 MR. STANOCH: Thank you, Judge, I'll be speaking
4 today on behalf of the plaintiffs. I think both parties'
5 letters set forth their positions quite clearly. I won't
6 belabor anything in those letters. I'll just respond very
7 briefly to Mr. Rubenstein to highlight a few points.

8 As Your Honor knows, Number 1, discovery
9 confidentiality orders do not trump the rights of access in
10 this case. Just because there is a protective order in place
11 does not mean Teva has discharged its burden to show good
12 cause for the continued confidentiality designations of these
13 documents at issue.

14 There's codefendants in this case, Judge, that
15 happens a lot. If Your Honor wants cases, we'll give you the
16 cases after this hearing, Judge, but Your Honor knows from
17 your experience and from otherwise, there are lots of
18 litigations, antitrust, consumer fraud, et cetera, et cetera,
19 where Courts evaluate confidentiality designations under
20 protective orders all of the time in cases, and we'll probably
21 get into the factors that weigh against the designations,
22 Judge, but I will note that the suggestion of nitrosamine is a
23 new issue and rapidly evolving. That does not negate the fact
24 that a lot of these documents are, in fact, years or many
25 years old, and, in fact, at least one of these documents

1 relates to a, publicly, an article about detecting
2 contamination in the API including nitrosamines from 2006, and
3 I'm sure we'll get to that. But I'll stop there, Judge.

4 THE COURT: All right. Very well. Let me ask both
5 of you a question to start with, the public access question.
6 Have the documents that are before me now, the 23 documents,
7 been presented in connection with any adjudicatory matter in
8 this case, any motion, et cetera?

9 MR. STANOCH: Judge, if I may, I think I know what
10 you're getting at. I believe the answer is no, that these are
11 -- at this stage, these are discovery materials. They have
12 not been appended or attached to motions or pleadings filed
13 with the Court, so to the extent Your Honor is getting at
14 whether it's public access versus the confidentiality
15 standard, I think it would be the confidentiality standard
16 today, but I would say, and maybe for another day, but Your
17 Honor may want to consider, these were all deposition exhibits
18 from the many depositions taken, and it's very likely they
19 will be appended to substantive pleadings, such as the motion
20 for class certification, if and when there's summary judgment
21 motions, we file oppositions, et cetera.

22 THE COURT: All right.

23 MR. RUBENSTEIN: And just following up on that --

24 THE COURT: And do you agree, Mr. Rubenstein, am I
25 pronouncing that correctly?

1 MR. RUBENSTEIN: Yes, you are. Thank you, Your
2 Honor. I do agree with that, and just getting to the
3 deposition piece of it, you know, so as to the extent any of
4 these documents were used at a deposition, Teva submitted
5 confidentiality designations after every deposition and
6 specifically marked all of these documents as confidential,
7 so, yeah, I agree with Mr. Stanoch.

8 THE COURT: Bear with me for a second here. As I
9 said, I intended to go through this document by document, and
10 I'm doing it in the order in which they appear in Teva's
11 letter to me, in submitting the documents, and I'm going to
12 just use the last several digits of the Bates numbers to make
13 the initial designation of the documents.

14 And the first document that I wanted to talk about --
15 and bear with me as I pull it up. This is a document that has
16 -- I'm just going to use the last four digits for this
17 document, 6479. It's a lengthy document, over 200 pages long,
18 and it does seem to provide information with respect to the
19 formulation for the finished dose of Valsartan and its active
20 pharmaceutical ingredient.

21 Is there more you wanted to say with respect to this
22 document, Mr. Rubenstein?

23 MR. RUBENSTEIN: Not so much. I mean, I think you
24 hit the nail on the head that this does, you know, this shows
25 the recipe. You know, it shows the master formula on how the

1 product was made. It's not just the ingredients used or the
2 materials used, it's how they're combined, processes that are
3 used. And, you know, I think again, you can't just look at
4 this case in a vacuum and, you know, these sort of processes
5 and ways that materials are combined are also used for other
6 products. And, you know, so even though this is Valsartan
7 and, you know, it's a relatively old document, I acknowledge
8 that, but, you know, it still shows the formula and that is
9 highly proprietary. It's something that Teva does not share.
10 You know, Teva is involved in patent litigation and, you know,
11 part of the things that they try to do is design around
12 patents, there's no secret there, and, you know, this shows
13 proprietary processes for doing that, and I think it should
14 remain confidential.

15 THE COURT: Mr. Stanoch?

16 MR. STANOCH: Not much to add besides our letter,
17 Judge. Obviously the age and staleness of the information we
18 think is a factor against continued confidentiality. The
19 products aren't sold in the United States anymore, I believe,
20 at least Teva stopped selling the Valsartan subject to this
21 document in the United States after the recalls. And to the
22 extent it identifies, you know, certain things like the
23 solvents that are supposed to be used or not during the
24 manufacturing process, just the names of the types of
25 solvents, that's a critical issue for the public safety,

1 health, and importance factor, given that recycled solvents
2 were one of the routes of the contamination. So we think that
3 weighs against confidentiality as well.

4 THE COURT: All right. I have -- I have reviewed the
5 document and have considered counsels' arguments. I do note
6 that I'm applying the, as my test, the protective order's
7 provisions with respect to designation of documents. I do
8 have an affidavit from Teva in connection with their request
9 to maintain this document as sealed, and having considered all
10 of that, in that regard, Mr. Binsol's affidavit -- Binsol is
11 B-I-N-S-O-L -- I think that Teva has shown that in good faith,
12 it believes that this document could cause it competitive harm
13 and it should remain sealed at this time.

14 The fact that it is more than ten years old does not
15 mean that it wouldn't -- couldn't cause competitive harm. So
16 this document will remain sealed.

17 The next document I have has the last four numbers,
18 as I pull it up, 8430. I'm pulling it up now. This is the
19 drug master file excerpt for Valsartan B-H-E-U-R.

20 Mr. Rubenstein, did you want to elaborate any more on
21 this document?

22 MR. RUBENSTEIN: Not so much. As you said, this is
23 the drug master file for Valsartan and, you know, by its
24 nature is confidential. You know, it would also implicate
25 some third-party interests as this is Mylan's DMF and Teva is

1 obligated to keep this confidential.

2 THE COURT: All right. Mr. Stanoch?

3 MR. STANOCH: Your Honor, this document is much more
4 brief than the other one.

5 THE COURT: Yes.

6 MR. STANOCH: Two pages, Judge. It shows a chemical
7 structure change. I mean, Your Honor can Google Valsartan's
8 synthesis valine methyl ester and you will get dozens and
9 dozens and dozens of pictures of these chemical structures.
10 We did not attach it for brevity, but there's nothing
11 proprietary. In fact, the patents would show the chemical
12 structures at issue.

13 And on the second page, it is just literally the
14 names of five solvent views including water. We don't think
15 this would result in significant competitive harm. Today,
16 Mylan hasn't said it would cause significant harm to them. We
17 think this one is different than the last document.

18 THE COURT: What does advance -- how does it advance
19 the interests in public health and safety to unseal this?

20 MR. STANOCH: [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

1

2 And I respectfully suggest that that's really
3 flipping the inquiry on its head. It's Teva's burden to
4 justify good cause for sealing, versus our obligation or the
5 public's obligation to say it should not be sealed. And I
6 think we've rebutted Teva's showing that this one should be
7 sealed.

8 THE COURT: Mr. Rubenstein, anything else on this
9 issue?

10 MR. RUBENSTEIN: No, and I know counsel for Mylan is
11 also on this call. You know, counsel for Mylan did not know
12 that this document was at issue, so I don't know if Mr. Stoy
13 would like to speak up about why this document should remain
14 confidential.

15 MR. STOY: Thank you, Mr. Rubenstein. Judge
16 Vanaskie, this is Frank Stoy. As you know, I represent Mylan
17 in this litigation. Mr. Rubenstein is correct.

18 You know, we weren't really given the opportunity to
19 assert a position on this document one way or the other. We
20 weren't part of the negotiations with plaintiffs about it. We
21 would take the position, Your Honor, that this is a
22 confidential document, should remain confidential. This is
23 part of the closed portion of the drug master file for Mylan's
24 API, and furthermore, this is the type of information that the
25 FDA would redact in establishment inspection reports that are

1 made public.

2 So although this is not a document that was
3 necessarily used with one of our witnesses, and it's not a
4 issue for us, to the extent this is Mylan's information, we
5 would maintain that this is a confidential document and at
6 this point should remain sealed.

7 THE COURT: All right. Thank you very much.

8 Any rebuttal, Mr. Stanoch?

9 MR. STANOCHE: I would just say that if it was part of
10 the closed part of the DMF, drug master file, Judge, Mylan
11 could not and would not give it to Teva in the first place and
12 it was produced to Teva, which prima facie shows that this was
13 part of the, quote, open part of the DMF which cuts against
14 any highly sensitive Mylan confidentiality interest.

15 MR. STOY: And again, Your Honor, I don't have the
16 document in front of me today, so I can't even verify whether
17 what Mr. Stanoch said is correct or not. This may be a
18 document that was shared with Teva after the fact when the
19 nitrosamine issue came to life. So I can't elaborate on that
20 one way or the other.

21 THE COURT: All right. Thank you. On this document,
22 Teva has shown that in its view and in good faith, it should
23 remain confidential. I did ask the question about the
24 interest in public health and safety, because I think that's a
25 factor when I'm balancing the interests here, and it hasn't

1 been shown to me that it needs to be disclosed for public
2 health and safety reasons. So this document, I guess it's
3 508430, will remain sealed. Let me verify that. That's
4 correct. All right?

5 So let's proceed to the next document. This is a
6 purchase order. I believe it's from November of 2012, and the
7 last digits on the document are 20166.

8 Mr. Rubenstein?

9 MR. RUBENSTEIN: The API industry is very highly
10 competitive and prices that API manufacturers charge their
11 customers and vice versa are just not publicly available. We
12 think this is one of the, you know, a very highly sensitive
13 document and all of the other documents that are being
14 produced, you know, the pricing information is being redacted,
15 you know, just because it's from 2012, you know, shouldn't
16 negate the fact that, you know, it shows quantities purchased,
17 the price. Again, it's just I think on its face highly
18 confidential and speaks for itself.

19 THE COURT: All right. Mr. Stanoch?

20 MR. STANOCH: Judge, quite simply, this is very, very
21 stale information. Teva has not shown how nearly a ten year
22 old purchase order is going to show harm. This is a purchase
23 order for an entity that no longer exists that's been acquired
24 by Teva, for API that that entity no longer buys from ZHP for
25 the U.S. market, hasn't done so for years, being shipped to a

1 legacy facility in Malta, which no longer operates now for a
2 number of years.

3 Teva hasn't made a specific showing how today, nine-
4 or ten year old pricing information is going to hurt it today
5 in the U.S. market for Valsartan API.

6 MR. RUBENSTEIN: Your Honor, if I could just briefly
7 respond.

8 THE COURT: You may.

9 MR. RUBENSTEIN: It's correct that this is an Actavis
10 purchase order, but Actavis is very much a part of Teva. The
11 fact that the manufacturing site has been closed is
12 irrelevant, you know, products removed from that manufacturing
13 site to a different one. You know, it shows quantities which
14 are, I think, very important here, you know, showing how much
15 Teva purchases is highly relevant, and would give it a
16 competitive disadvantage if it were to be revealed.

17 And again, you know, it's not -- this case is --
18 these issues on confidentiality are not limited to this
19 litigation. These could reveal overall business strategies
20 that Teva employs for its other products. And the fact that
21 Teva may not be purchasing Valsartan from ZHP currently, it is
22 purchasing other active pharmaceutical ingredients from them,
23 and, you know, like I said, it shouldn't be looked at in a
24 vacuum as just related to Valsartan in the U.S. market.

25 THE COURT: Given the fact that it's not part of a

1 work filing in an adjudicatory proceeding, I believe that Teva
2 has acted in good faith in designating this document as
3 confidential and having it sealed, and the seal for 20166 will
4 remain in place.

5 We're going to move to the third category of
6 documents dealing with testing methods. The first document I
7 have in this category has the last five digits of the Bates
8 number being 21073. It is a July 13, 2018, email concerning
9 testing for NDMA.

10 Mr. Rubenstein?

11 MR. RUBENSTEIN: As you said, this is an email from
12 July of 2018 literally weeks after the nitrosamine impurity
13 issue was uncovered and revealed to Teva, and, you know, this
14 discusses how they're dealing with this issue. It's a --
15 they're just learning it, it has action items from different
16 departments within the company showing their strategy for
17 tackling this issue and testing it.

18 As I said earlier, this is -- especially at this
19 time, with an evolving issue, it still is and every company is
20 treating it differently, and for other companies to see how
21 Teva's employing its test methods and what it's doing would
22 put it at a significant competitive disadvantage.

23 THE COURT: All right. Mr. Stanoch?

24 MR. STANOCH: Judge, Teva and its competitors have
25 collaborated to disclose what their testing methods are for

1 NDMA and other nitrosamines today. They've disclosed it to
2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 document doesn't have test results, doesn't have any indicia
6 that we saw in the first two documents we saw.

7 [REDACTED]

8 [REDACTED]

9 [REDACTED]

10 be flip, Judge. That's basically me telling my colleague,
11 where can -- go check with Home Depot and Lowe's for the
12 Shop-Vac. So we don't think this has any significant
13 competitive harm today to Teva.

14 THE COURT: All right. Again applying the standard
15 I've been applying thus far, and that is relying upon the
16 affidavit of Mr. Binsol, although it is, in large measure, not
17 very detailed, it does provide a basis for determination that
18 Teva in good faith has believed that this document should
19 remain confidential and it shall remain sealed.

20 The next document in this category has the last five
21 digits as 42637. Let me pull it up, please. I should have
22 had all these teed up, but I have too many windows open
23 already. So I ran out of space.

24 This is an August 14, 2018, document. It's called
25 [REDACTED]

1 Mr. Rubenstein, is there anything else you wanted to
2 add to this?

3 MR. RUBENSTEIN: No, this is very similar to the July
4 email. It's still in the very beginning of the discovery of
5 these nitrosamine impurities, you know, and while there is
6 some public information contained within this document, it
7 does also, you know, it takes that public information and
8 describes how Teva is going to deal with it, which again is
9 highly proprietary. There's comments throughout the document.
10 This is not a final document, you know, showing again, that
11 this is strictly meant for internal use and not to be shared.

12 THE COURT: All right. All right.

13 MR. RUBENSTEIN: It doesn't want to reveal its
14 thought processes.

15 THE COURT: Mr. Stanoch?

16 MR. STANOCH: Thank you, Judge. I just want to put
17 on the record we will of course throughout today, follow all
18 of Your Honor's rulings. I just want to state for the record
19 that by doing so, we are not waiving any subsequent challenge
20 to the extent any document ruled on today might be attached to
21 a filing, in which case there's a different analysis, as Your
22 Honor knows.

23 THE COURT: Yes.

24 MR. STANOCH: Thank you, Judge. With that said, the
25 only other thing I would add aside from what I said before in

1 our letter or for the last document is, yes, it's a draft,
2 yes, a lot of the comments are important public health and
3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 THE COURT: And it is, of course, a draft document
10 that contains many bullet -- comment bubbles. It is not in
11 final form for sure. I believe it has been appropriately
12 designated as confidential and it shall remain sealed, at
13 least for the time being.

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 in February of 2020.

19 Mr. Rubenstein?

20 MR. RUBENSTEIN: Again, Your Honor, you know, it
21 shows Teva's testing processes, what it tests, what tests it
22 used. You know, I think the same argument which you're going
23 to apply for all of the documents within this category.

24 THE COURT: Same arguments might apply, but not
25 necessarily the same result. Just to let you know.

1 MR. RUBENSTEIN: Understood.

2 THE COURT: But on this document, Mr. Stanoch,
3 anything else?

4 MR. STANOCH: It's just emphasized again, Your Honor,

5 [REDACTED]

6 [REDACTED]

7 is nothing proprietary about Teva. It's not showing Teva's
8 testing, it's certainly not showing Teva's testing results.

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 So the fact that that's coming out through a common
13 tool, we don't think it's going to show anything sensitive or
14 proprietary to Teva, let alone any harm flowing from this
15 today.

16 THE COURT: As to this document, I do find that it
17 should remain sealed and it shall remain sealed at least for
18 the time being.

19 Next document is 158463. This is an email thread,
20 the first on the top email is dated June 5 -- June 15, 2016,
21 and I had a little bit of trouble understanding this email.
22 Maybe you could elaborate a little bit on it, Mr. Rubenstein.

23 [REDACTED]

24 [REDACTED]

25 MR. RUBENSTEIN: So this -- I mean, I can see how you

1 are a little confused by it. It's a little confusing on its
2 face. I think first of all, much of the document relates to a
3 [REDACTED]
4 nothing to do with this litigation, as you know.

5 It's only the top part of the email thread that
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]

16 THE COURT: Mr. Stanoch?

17 MR. STANOCH: I would only add to what we submitted,
18 Your Honor. We're talking about a document over five years
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

1 THE COURT: Mr. Rubenstein, how is Teva harmed if
2 this document is unsealed?

3 MR. RUBENSTEIN: Again, you know, it shows how Teva
4 tests for impurities and what it's doing internally to make
5 sure that these impurities are addressed properly. And again,
6 it also shows the costs of what an impurity test is, at least
7 with respect to Teva, and --

8 THE COURT: I would think the costs would be public
9 information.

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THE COURT: My initial inclination was to unseal this document. I'm going to study it further and give you my determination in writing.

And I will tell you my initial inclination is to unseal the next document, so you can approach it from -- with that understanding. It has Bates number 101997. This is a March 18, 2014, email. Subject is General Toxic Impurities.

Why should this remain sealed, Mr. Rubenstein?

MR. RUBENSTEIN: So I guess contrary to plaintiffs'

1 submission, this was not marked confidential to hide anything
2 embarrassing. In fact, it shows the opposite, that Teva goes
3 above and beyond what it should be doing in terms of testing,
4 but again, while it refers to a publicly available link here,
5 you know, there are different ways of testing these things and
6 this is the one that Teva chose. And revealing that, again,
7 to the competitors, direct competitors who are codefendants in
8 this litigation, would put it at a competitive disadvantage.

9 THE COURT: All right. Mr. Stanoch?

10 MR. STANOCH: Judge, that's seven-plus years ago, one
11 Teva employee told another, hey, we should -- one of our
12 suppliers says there's no genotoxic impurities, you might want
13 to double-check that, take a look at this 2006 article that's
14 generally helpful. There's nothing proprietary about that.
15 There's nothing about specific test results, testing methods,
16 et cetera, let alone the age of this information. It's simply
17 not of the same caliber of documents that we've seen so far
18 even today in terms of competitive sensitivity.

19 THE COURT: Yeah, I do agree. My inclination was to
20 unseal this. It is, Number 1, more than seven years old. It
21 refers to an article that was published in 2006, so it's
22 something that is in the public marketplace, and I don't see
23 -- I, frankly, don't see how this could cause competitive harm
24 to Teva. I have deferred to Teva's judgment on this, it is
25 true, but this one seems to me to stand in a different light,

1 and, therefore, will direct that 101997 will be unsealed.

2 This brings us to the fourth category of documents,
3 and these are audit reports and related communications. And
4 the first audit report at issue, has as its last several
5 digits in the Bates numbering sequence, 247059, and, you know,
6 let me know whether you think we can address these as a whole,
7 rather than each individual document, since they are all audit
8 reports.

9 MR. RUBENSTEIN: I think that makes sense. You know,
10 I think the rationale is going to be the same as to why the
11 documents should remain confidential for all of them, and
12 there are one, two, three, four, five, six, seven, eight, nine
13 documents, and I don't know if you want to read or if you
14 would like me to read the Bates numbers into the record, but
15 there are nine distinct documents that are being challenged.

16 Two of them are actually identical documents with
17 different Bates numbers, so there's really eight different
18 audit reports. Some of them relate to Mylan and some of them
19 relate to ZHP, who are the two API suppliers for Teva for
20 Valsartan at issue in this litigation, and the two arguments
21 as to why they should be dedesignated is, one, is they're old,
22 and two, that they would be embarrassing if released, and, you
23 know, both of those arguments should be rejected.

24 [REDACTED]

25 [REDACTED]

1 [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 You know, again, you know, I said this earlier, but
5 plaintiffs reference in their letter specifically with respect
6 to the audit report, that these reviews in depositions and
7 again, Teva designated all of these documents as confidential
8 after each of the depositions.

9 Not only is it Teva's internal process of how it
10 audits its vendors and suppliers, but this also has
11 third-party information that Teva just is not at liberty to
12 share. It doesn't share this information with the FDA unless
13 it's asked, but, you know, then it would need specific
14 permission from its vendor to do so, you know.

15 You know, they say on their face that they're
16 confidential and not to be duplicated. You know, I think it
17 would cause clear harm to Teva if its suppliers learned that
18 Teva can't keep this type of information confidential.

19 THE COURT: Thank you. I have one question first of
20 you, Mr. Rubenstein, and then I'll hear from Mr. Stanoch.

21 The duplicate documents, are they 118147 and 118210?

22 MR. RUBENSTEIN: Yes.

23 THE COURT: Okay. All right.

24 Mr. Stanoch?

25 MR. STANOCH: Thank you, Judge. Just generally,

1 we're not contending for any documents that Teva waive any
2 confidentiality designations by virtue of using the documents
3 in a deposition some way or that they were used. Just so it's
4 clear, we're not saying that, so maybe I can save
5 Mr. Rubenstein some breath every time you get to a new
6 category in that regard.

7 I would only add to our letter, Judge, that a number
8 of these -- well, first of all, all of them are over three
9 years old at this point. A number of -- some of them even
10 being back a decade or about that far. These audit reports,
11 they were meticulously redacted by Teva for other products or
12 things that did not specifically relate to the Valsartan and
13 nitrosamine issues in this case. This goes to the heart of
14 [REDACTED]

15 [REDACTED]
16 [REDACTED]

17 So this is sort of at the top of terms of what public
18 interest importance might be in health and safety, when you
19 combine the fact that some of these things are quite stale at
20 this point, and that Teva had certain physical observations by
21 auditors during walk-throughs ten years ago, eight years ago,
22 et cetera, at plants that they may not even be buying from
23 today. It's unclear how that would specifically competitively
24 harm them today.

25 THE COURT: Thank you, Mr. Stanoch.

1 Go ahead, Mr. Rubenstein.

2 MR. RUBENSTEIN: Sorry, Your Honor. Just again, this
3 is not just about Valsartan, it's about Teva's processes and
4 its evolving audit processes over time. So the fact that some
5 of these documents may be older than others should not weigh
6 against their designation. Again, it just shows Teva's
7 internal processes, how it evolved, what it looks for, what it
8 thinks is important and, you know, revealing that to its
9 competitors would cause harm.

10 THE COURT: Yeah, these documents, the audit reports,
11 they are listed in the letter -- I guess the letter was filed
12 under seal. I'll just list them by number, the last several
13 digits: 247059, 318831, the next is 320639, the next is
14 399168, then there's 118147, 118210, and there's 244215, next
15 is 244725, and finally, 318608. These are the audit reports
16 themselves. Some are dated, some are fairly recent.

17 320639 -- unless my handwriting is wrong -- we'll
18 just stick with 318831 is from March of 2018. They do, I
19 think, reveal confidential information concerning the internal
20 processes of Teva, and could cause competitive harm, and they
21 shall remain sealed.

22 Now, there are related email chains that I am not
23 convinced right now should remain sealed. The first is 73283,
24 and I'm going to pull that up now. The top email in this
25 email thread is dated October 16, 2018.

1 Why should I continue to have this document remain
2 sealed, Mr. Rubenstein?

3 MR. RUBENSTEIN: Well, similar to the audit reports,
4 Your Honor, the email correspondence, the back and forth about
5 how the audit reports are finalized and drafted and reviewed
6 and completed, again shows what Teva, its process is behind
7 the scenes.

8 And I want to address, you know, what was in
9 plaintiffs' letter about this particular email. Mr. Veretto,
10 who is the author of this email, was deposed by plaintiffs
11 over the course of two days, and he was questioned about this
12 email, and what he said was, you know, plaintiffs
13 characterized him saying that the auditors are being too
14 critical of ZHP, but what he actually said at his deposition
15 was that this report is critical, it's too important, and with
16 respect to it being labeled as privileged and confidential,
17 you know, Mr. Veretto consulted with legal throughout this
18 entire process, and he testified at his deposition that legal
19 asked him to inform his people -- Mr. Veretto was the head of
20 the quality organization at this point, and he informed his
21 people to -- he was informed by legal to mark these as
22 privileged and confidential, at least the drafts, and he was
23 just following the directions of his counsel.

24 He's not a lawyer, but that's what he was asked to
25 do, and so he pushed that along. And just like the reports

1 are entitled to confidentiality, the internal discussions
2 around those reports are entitled to confidentiality,
3 especially when it comes to, you know, critical things as, you
4 know, giving a company a final rating. You know, how Teva
5 goes about coming up with that final rating is the very heart
6 of its internal processes.

7 THE COURT: All right. Thank you.

8 Mr. Stanoch?

9 MR. STANOCH: Judge, we're not arguing about the
10 merits or factual inferences to be drawn from sentences in
11 this document today. We're not here to discuss whether the
12 document is privileged or any other document is legally
13 privileged. We're talking about the confidentiality of this
14 particular email, and we don't believe Teva has shown that
15 there's any confidentiality interests that legitimately
16 attaches to this email. It's devoid of any proprietary
17 information, competitive sensitivity. It's of the highest
18 level almost administrative in terms of what to label a
19 document and someone's review of it and who's going to look at
20 something next. There's simply nothing here that could result
21 in significant competitive injury to Teva today.

22 THE COURT: Yes, I agree with Mr. Stanoch. I don't
23 see how this document can cause competitive harm to Teva.
24 It's not very informative and, therefore, we'll direct that it
25 be unsealed.

1 The next document is 244213. This is an email, the
2 top e-mail is dated September 5, 2011. It deals with an audit
3 on Valsartan, and it's a email that is authored by Igor
4 Lifshitz, L-I-F-S-H-I-T-Z.

5 Why should this document remain sealed?

6 MR. RUBENSTEIN: There's a few. Again, it goes to
7 the processes of Teva's audits, you know, the information in
8 here will ultimately be contained in the audit report, but it
9 also raises third-party interests in terms of, you know, what
10 Teva is saying about its vendors, and if this information were
11 to get out, it could competitively harm Teva with respect to
12 its other vendors.

13 I know that, again, this is an old document, but so
14 are some of the audit reports that have been deemed to be
15 sealed at this time, and it directly relates to those
16 documents.

17 THE COURT: All right. Mr. Stanoch?

18 MR. STANOCH: Judge, this email is very similar to
19 the last one, that the document itself is devoid of any
20 proprietary or commercially-sensitive information. It's from
21 2011, very high-level statements, far from embarrassing, it's
22 saying that ZHP is one of the best Chinese API companies, so I
23 can't understand how there would be any competitive harm from
24 ZHP hearing about that, and it goes to the heart of these
25 issues and that it references generally things or quality

1 issues, but without getting to the specifics because the audit
2 report we've looked at before and for now is staying
3 confidential. So there's simply nothing here that would
4 result in harm to Teva today from this ten year old email.

5 THE COURT: Yeah, I agree with Mr. Stanoch. I can't
6 see a competitive harm being caused by unsealing this email
7 from ten years ago. And so, therefore, direct that it be
8 unsealed.

9 [REDACTED]

10 [REDACTED]

11 Why should this document remain sealed,
12 Mr. Rubenstein?

13 MR. RUBENSTEIN: So this document shows the very
14 essence of what Teva's senior management was thinking about

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 And again, this nitrosamine impurities issue is

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 THE COURT: All right. Mr. Stanoch?

24 MR. STANOCH: Aside from the obvious vintage of the
25 document being approximately three years old, Your Honor, it

1 goes to the heart of the public interest in the health and
2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 That's a real issue during the middle of these
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 the audit report itself. We've already addressed the audit
11 report itself. And a lot of the information in terms of the
12 ultimate findings and cause of the contamination, this is all
13 in the public discourse now in terms of the literature of the
14 public agencies, et cetera.

15 THE COURT: Thank you. Unlike the other -- go ahead,
16 Mr. Rubenstein.

17 MR. RUBENSTEIN: Go ahead.

18 [REDACTED]
19 [REDACTED]
20 [REDACTED]
21 [REDACTED]
22 [REDACTED]
23 [REDACTED]
24 The next category of documents, I think there are
25 [REDACTED]

1 [REDACTED]

2 Just bear with me, please.

3 Why should this document remain sealed,

4 Mr. Rubenstein?

5 MR. RUBENSTEIN: So, again, you know, this is again
6 at the very beginning of the nitrosamine impurity issues and
7 this is actually -- so this is when it first learned of a
8 potential impurity in its -- in Teva's Mylan's API. This is
9 from November of 2018, and, you know, this is not just an

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 THE COURT: All right. Mr. Stanoch?

17 MR. STANOCH: Your Honor, I suggested that we're not
18 revealing anything proprietary or thought processes or
19 anything of that caliber of intellectual rigor. I mean, Teva
20 essentially announced to the world that it had recalled and
21 stopped selling Valsartan that contained API from ZHP and

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

1 used up a lot that it bought five years ago and that it may
2 have some API left from a lot they bought last month. That's
3 not going to result in competitive harm then, it certainly
4 doesn't result in competitive harm to Teva now.

5 THE COURT: Let me ask Mr. Rubenstein and then I'll
6 ask you to comment on this question as well, Mr. Stanoch, and
7 that is: Why shouldn't I direct that part of this document be
8 unsealed, and that is the part of the document that is simply
9 an inventory listing of the Valsartan product on hand, the
10 attachment to material accountability. Why should that not be
11 unsealed? Yeah.

12 MR. RUBENSTEIN: I'm just making sure that it's
13 Attachment 2, Material Accountability, that we're talking
14 about.

15 THE COURT: That's what we're talking about right
16 now, yes.

17 MR. RUBENSTEIN: I suppose we could probably live
18 with just redacting everything else, except for Attachment 2.

19 THE COURT: All right. Let's move to Attachment 3 as
20 well, which is Product Accountability.

21 MR. RUBENSTEIN: Before committing to anything, I
22 would probably want to compare what's in here to Teva's recall
23 notice, and to the extent that this information is contained
24 in Teva's recall notice, then this could probably be left
25 unredacted as well.

1 THE COURT: All right. Mr. Stanoch?

2 MR. STANOCH: Your Honor, if you're inclined to
3 partially unseal some of this, we're fine with that as a
4 compromise. I don't know if the touchstone should be whether
5 Teva's recall notices already disclosed all of this
6 information, per se. I think at least these two attachments,
7 regardless of what Teva announced to the public, in terms of
8 the recall, it's simply a manifest -- it doesn't show any of
9 the things we saw in the purchase order, it doesn't show
10 quantity, it doesn't show prices. On its face, there's just
11 simply no competitive sensitivity then or, frankly, now.

12 But, however Your Honor would like to proceed.

13 THE COURT: Yeah, I believe it would be appropriate
14 to unseal Attachments 2 and 3 to this document. The rest of
15 it will remain sealed.

16 That brings us then to 950663. Give me a second.

17 [REDACTED]

18 All right. Mr. Rubenstein?

19 MR. RUBENSTEIN: So the fact that this is an Actavis
20 document should not take any consideration into this decision
21 here. Actavis is very much a part of Teva. This shows how
22 Teva evaluates change controls and the fact that it's an
23 eight-year-old document is irrelevant, because it reveals its
24 processes and how it determines whether change controls are

25 [REDACTED]

1 [REDACTED]
2 copy without permission, controlled documents, very evident
3 that this is the type of information that Teva does not reveal
4 to the public, it intends to keep confidential, and I guess it
5 [REDACTED]

6 [REDACTED]
7 [REDACTED]

8 THE COURT: Mr. Stanoch?

9 MR. STANOCH: Besides the obvious, beyond the
10 substantive document, Your Honor, which is not irrelevant, I
11 would add. I'd also add that nothing in Mr. Binsol's
12 declaration substantiates or comes close to showing that
13 whatever Actavis might have done eight, nine years ago in
14 terms of assessing Valsartan, if that's remotely close to what
15 it does today. They're under an obligation to make a specific
16 showing with particularity and not with broad statements that
17 competitive harm will result and how, and I don't think
18 they've shown that what a legacy entity did eight or nine
19 years ago is still relevant to what Teva now does today,
20 putting completely aside the facts that obviously this is a
21 better product they no longer sell in the U.S., and that it
22 [REDACTED]

23 [REDACTED]
24 [REDACTED]
25 [REDACTED]

1 THE COURT: All right. I'm going to take this
2 document under further study. I'm going to study it further
3 before making a final determination whether it should be
4 unsealed in whole or in part, and that will bring us to the
5 final document.

6 That's 158540, and this falls under the category of
7 health assessment document. Please give me a second to pull
8 it up.

9 All right. Mr. Rubenstein?

10 And I should note that this is actually email
11 concerning a health assessment, and the first email, the top
12 page is dated July 5, 2018.

13 MR. RUBENSTEIN: Again, very beginning of discovery
14 of the nitrosamine impurities and Teva's internal evaluation
15 and getting its arms around it and coming up with toxicology
16 calculations. You know, again showing Teva's internal
17 processes and thoughts, the FDA has come up with its at least
18 interim limits, and this is just, you know, this is how Teva
19 views it, and it's just a discussion -- it's not just a
20 discussion about a proposed NDMA limit. It reveals Teva's
21 internal thought processes about how it comes up with those,
22 how limits are calculated.

23 And again, you know, at this time, early July of
24 2018, people are scrambling and everybody is just sort of
25 trying to figure out what's going on because it's a brand-new

1 issue for the industry and, you know, showing how Teva
2 evaluated the issue and thought about it at the time, is
3 proprietary.

4 THE COURT: All right. Mr. Stanoch?

5 MR. STANOCH: I would agree, Your Honor, that this is
6 right in the middle with the revelation in the summer of 2018
7 about the NDMA contamination, and that's why this document is
8 so important from a public interest, health and safety
9 perspective. Aside from being over three years old and not
10 having any proprietary or commercially-sensitive testing,
11 testing methods results itself, this is discussion in the
12 abstract about limits. This is nothing about how Teva -- what
13 Teva tested its own product or otherwise and the results of
14 that. That's not even this.

15 It's showing that Teva's toxicologist, lead
16 toxicologist Mr. Nudelman, N-U-D-E-L-M-A-N, is disagreeing
17 about a higher limit that's being suggested as being
18 inconsistent with industry standard ICH guidelines. There's
19 -- there can't really be anything more important to the public
20 when it comes to one of the sellers of one of the drugs with
21 the contamination that was being recalled, and that their
22 toxicologist is saying, it's more toxic than we think, why are
23 we pushing for a limit that's inappropriate.

24 THE COURT: Yeah, I've looked carefully at this
25 document. I don't see a competitive disadvantage to Teva from

1 it being unsealed. It does reveal an internal debate about
2 what the appropriate daily limit for NDMA should be, but I
3 don't think that reveals proprietary or confidential
4 information, and I'll direct that it be unsealed.

5 All right. I think that covers all of the documents
6 that are at issue here. I'll wait to get the transcript.

7 In the meantime, I'll look at a few documents that I
8 indicate that I would study further and issue a written -- a
9 brief written decision on those few documents.

10 Is there anything else to discuss today?

11 MR. RUBENSTEIN: Nothing further, Your Honor.

12 MR. STANOCH: Nothing from plaintiffs. Thank you,
13 Judge.

14 THE COURT: Thank you all very much.

15 RESPONSE: Thank you, Your Honor.

16 (11:25 a.m.)

17 | Page

18

19 I certify that the foregoing is a correct transcript
20 from the record of proceedings in the above-entitled matter.

22 /S/ Karen Friedlander, CRR, RMR
Court Reporter/Transcriber

24 September 13, 2021
Date

<p>/</p> <p>/S [1] - 39:22</p> <p>1</p> <p>1 [2] - 6:8, 23:20 101997 [2] - 22:22, 24:1 10:13 [2] - 1:8, 2:2 118147 [2] - 25:21, 27:14 118210 [2] - 25:21, 27:14 11:25 [1] - 39:16 13 [4] - 1:7, 2:2, 16:8, 39:24 14 [1] - 17:24 15 [1] - 20:20 15219 [1] - 1:20 158463 [1] - 20:19 158540 [1] - 37:6 16 [1] - 27:25 1717 [1] - 1:15 18 [1] - 22:23 1835 [1] - 1:12 19103 [2] - 1:13, 1:16 1:19-md-02875-RBK-KW [1] - 1:5</p> <p>2</p> <p>2 [3] - 34:13, 34:18, 35:14 200 [1] - 8:17 2006 [3] - 7:2, 23:13, 23:21 2011 [2] - 30:2, 30:21 2012 [2] - 14:6, 14:15 2014 [1] - 22:23 2016 [1] - 20:20 20166 [2] - 14:7, 16:3 2018 [9] - 16:8, 16:12, 17:24, 27:18, 27:25, 33:9, 37:12, 37:24, 38:6 2020 [1] - 19:18 2021 [3] - 1:7, 2:2, 39:24 21073 [1] - 16:8 23 [1] - 7:6 244213 [1] - 30:1 244215 [1] - 27:14 244725 [1] - 27:15 247059 [2] - 24:5, 27:13 2900 [1] - 1:12</p>	<p>3</p> <p>3 [2] - 34:19, 35:14 318608 [1] - 27:15 318831 [2] - 27:13, 27:18 320639 [2] - 27:13, 27:17 38th [1] - 1:20 399168 [1] - 27:14</p> <p>4</p> <p>400 [1] - 1:16 42637 [1] - 17:21</p> <p>5</p> <p>5 [3] - 20:20, 30:2, 37:12 508430 [1] - 14:3</p> <p>6</p> <p>6479 [1] - 8:17</p> <p>7</p> <p>73283 [1] - 27:23 756-0160 [1] - 1:23</p> <p>8</p> <p>8430 [1] - 10:18 856 [1] - 1:23</p> <p>9</p> <p>950663 [1] - 35:16</p> <p>A</p> <p>a.m [2] - 1:8, 39:16 A.M [1] - 2:2 above-entitled [1] - 39:20 abstract [1] - 38:12 access [4] - 5:1, 6:9, 7:5, 7:14 accountability [1] - 34:10 Accountability [2] - 34:13, 34:20 acknowledge [1] - 9:7 acquired [1] - 14:23 Actavis [7] - 1:17, 15:9, 15:10, 35:19, 35:21, 36:13 acted [1] - 16:2 ACTION [1] - 1:4 action [1] - 16:15</p>	<p>active [2] - 8:19, 15:22 add [7] - 9:16, 18:2, 18:25, 21:17, 26:7, 36:11 address [4] - 2:14, 2:22, 24:6, 28:8 addressed [2] - 22:5, 32:10 addressing [1] - 2:6 adjudicatory [2] - 7:7, 16:1 administrative [1] - 29:18 advance [2] - 11:18 advantage [1] - 4:18 affected [1] - 3:21 affidavit [4] - 5:2, 10:8, 10:10, 17:16 aforementioned [1] - 4:8 age [4] - 4:3, 4:6, 9:17, 23:16 agencies [1] - 32:14 ago [7] - 23:10, 26:21, 31:7, 34:1, 36:13, 36:19 agree [7] - 7:24, 8:2, 8:7, 23:19, 29:22, 31:5, 38:5 ahead [3] - 27:1, 32:15, 32:17 aided [1] - 1:24 ALFANO [1] - 1:19 ALL [1] - 2:1 almost [1] - 29:18 alone [2] - 20:14, 23:16 analysis [1] - 18:21 AND [1] - 1:5 announced [2] - 33:20, 35:7 answer [1] - 7:10 antitrust [1] - 6:18 API [13] - 5:12, 5:18, 7:2, 12:24, 14:9, 14:10, 14:24, 15:5, 24:19, 30:22, 33:8, 33:21, 34:2 appear [1] - 8:10 appended [2] - 7:12, 7:19 apply [3] - 4:8, 19:23, 19:24 applying [3] - 10:6, 17:14, 17:15 appreciate [1] - 2:18 approach [2] - 2:13, 22:21 appropriate [2] - 35:13, 39:2</p> <p>appropriately [1] - 19:11 Arch [1] - 1:15 arguing [1] - 29:9 argument [1] - 19:22 arguments [5] - 4:1, 10:5, 19:24, 24:20, 24:23 arms [1] - 37:15 article [3] - 7:1, 23:13, 23:21 aside [4] - 18:25, 31:24, 36:9 assert [1] - 12:19 assessing [1] - 36:14 assessment [3] - 5:22, 37:7, 37:11 assessments [1] - 5:22 attach [1] - 11:10 attached [2] - 7:12, 18:20 attaches [1] - 29:16 attachment [1] - 34:10 Attachment [3] - 34:13, 34:18, 34:19 attachments [1] - 35:6 Attachments [1] - 35:14 audit [19] - 5:20, 5:21, 24:3, 24:4, 24:7, 24:18, 25:6, 26:10, 27:4, 27:10, 27:15, 28:3, 28:5, 30:2, 30:8, 30:14, 31:1, 32:10 auditors [2] - 26:21, 28:13 audits [2] - 25:10, 30:7 August [1] - 17:24 author [1] - 28:10 authored [1] - 30:3 available [2] - 14:11, 23:4</p> <p>B</p> <p>B-H-E-U-R [1] - 10:19 balancing [1] - 13:25 based [2] - 4:3, 4:6 basis [1] - 17:17 Bates [6] - 8:12, 16:7, 22:22, 24:5, 24:14, 24:17 bear [3] - 8:8, 8:15, 33:2 beginning [3] - 18:4, 33:6, 37:13 behalf [2] - 2:6, 6:4</p>	<p>behind [1] - 28:6 belabor [1] - 6:6 believes [1] - 10:12 benchmark [1] - 4:20 best [1] - 30:22 better [1] - 36:21 beyond [2] - 23:3, 36:9 BINSOL [1] - 10:11 Binsol [3] - 5:2, 10:10, 17:16 Binsol's [2] - 10:10, 36:11 bit [2] - 20:21, 20:22 BOSICK [1] - 1:19 bought [2] - 34:1, 34:2 brand [1] - 37:25 brand-new [1] - 37:25 breath [1] - 26:5 brevity [1] - 11:10 Brian [2] - 2:6, 2:11 BRIAN [1] - 1:15 brief [4] - 4:9, 5:16, 11:4, 39:9 briefly [2] - 6:7, 15:6 bright [1] - 4:3 bring [1] - 37:4 brings [2] - 24:2, 35:16 broad [1] - 36:16 bubbles [1] - 19:10 bullet [1] - 19:10 burden [2] - 6:11, 12:3 business [5] - 3:8, 5:8, 5:13, 5:14, 15:19 buying [1] - 26:22 buys [2] - 5:12, 14:24 BY [3] - 1:12, 1:15, 1:19</p> <p>C</p> <p>calculated [1] - 37:22 calculations [2] - 5:22, 37:16 caliber [2] - 23:17, 33:19 cannot [1] - 5:10 carefully [1] - 38:24 case [10] - 4:11, 4:22, 5:10, 6:10, 6:14, 7:8, 9:4, 15:17, 18:21, 26:13 cases [5] - 3:2, 4:10, 6:15, 6:16, 6:20 categories [1] - 5:17 category [10] - 2:20, 16:5, 16:7, 17:20, 19:23, 24:2, 26:6,</p>
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<p>32:24, 37:6 caused[1] - 31:6 causing[1] - 4:17 Centre[1] - 1:20 certain[3] - 4:22, 9:22, 26:20 certainly[2] - 20:8, 34:3 certification[1] - 7:20 certify[1] - 39:19 cetera[7] - 6:18, 7:8, 7:21, 23:16, 26:22, 32:14 chains[1] - 27:22 challenge[1] - 18:19 challenged[1] - 24:15 challenging[1] - 3:16 change[3] - 11:7, 35:22, 35:24 characterized[1] - 28:13 charge[1] - 14:10 check[2] - 17:11, 23:13 chemical[3] - 11:6, 11:9, 11:11 Chinese[1] - 30:22 chose[1] - 23:6 cite[3] - 4:4, 4:9, 4:10 cited[1] - 3:3 CIVIL[1] - 1:4 class[1] - 7:20 clear[2] - 25:17, 26:4 clearly[1] - 6:5 close[2] - 36:12, 36:14 closed[3] - 12:23, 13:10, 15:11 codefendants[6] - 2:24, 3:4, 3:10, 5:14, 6:14, 23:7 collaborated[1] - 16:25 colleague[1] - 17:10 combine[1] - 26:19 combined[2] - 9:2, 9:5 coming[3] - 20:12, 29:5, 37:15 Commencing[1] - 1:8 comment[2] - 19:10, 34:6 comments[2] - 18:9, 19:2 commercial[1] - 4:15 commercially[2] - 30:20, 38:10 commercially- sensitive[2] - 30:20, 38:10 </p>	<p>committing[1] - 34:21 common[1] - 20:12 communications[2] - 5:21, 24:3 companies[4] - 3:21, 5:6, 16:20, 30:22 company[5] - 3:20, 3:22, 16:16, 16:19, 29:4 compare[1] - 34:22 competitive[25] - 3:14, 4:17, 4:18, 10:12, 10:15, 11:15, 14:10, 15:16, 16:22, 17:13, 23:8, 23:18, 23:23, 27:20, 29:17, 29:21, 29:23, 30:23, 31:6, 34:3, 34:4, 35:11, 36:17, 38:25 competitively[2] - 26:23, 30:11 competitors[7] - 2:25, 3:4, 3:11, 16:24, 23:7, 27:9 completed[1] - 28:6 completely[1] - 36:20 complex[1] - 5:6 compromise[1] - 35:4 computer[1] - 1:24 computer-aided[1] - 1:24 concerning[3] - 16:8, 27:19, 37:11 conducts[1] - 5:13 confidential[29] - 2:16, 3:1, 3:7, 3:9, 4:13, 8:6, 9:14, 10:24, 11:1, 12:14, 12:22, 13:5, 13:23, 14:18, 16:3, 17:19, 19:12, 23:1, 24:11, 25:7, 25:16, 25:18, 27:19, 28:16, 28:22, 31:3, 36:4, 39:3 confidentiality[15] - 6:9, 6:12, 6:19, 7:14, 7:15, 8:5, 9:18, 10:3, 13:14, 15:18, 26:2, 29:1, 29:2, 29:13, 29:15 confused[1] - 21:1 confusing[1] - 21:1 connection[2] - 7:7, 10:8 consider[1] - 7:17 consideration[1] - 35:20 considered[2] - 10:5, 10:9 considering[1] - 2:15 </p> <p style="text-align: center;">D</p> <p>daily[1] - 39:2 Date[1] - 39:24 dated[5] - 20:20, 27:16, 27:25, 30:2, 37:12 DAVID[1] - 1:12 days[1] - 28:11 deal[1] - 18:8 dealing[2] - 16:6, 16:14 deals[1] - 30:2 debate[1] - 39:1 decade[1] - 26:10 decision[2] - 35:20,</p> <p>direct[9] - 2:25, 3:3, 3:10, 23:7, 24:1, 29:24, 31:7, 34:7, 39:4 directions[1] - 28:23</p> <p>directly[2] - 5:4, 30:15 Director[1] - 5:3 disadvantage[4] - 15:16, 16:22, 23:8, 38:25 disagreeing[1] - 38:16 discharged[1] - 6:11 disclose[1] - 16:25 disclosed[4] - 4:17, 14:1, 17:1, 35:5 disclosure[1] - 4:24 discourse[1] - 32:13 discovery[5] - 3:18, 6:8, 7:11, 18:4, 37:13 DISCOVERY[1] - 1:6 discuss[2] - 29:11, 39:10 discusses[1] - 16:14 discussion[3] - 37:19, 37:20, 38:11 discussions[1] - 29:1 distinct[1] - 24:15 DISTRICT[2] - 1:2, 1:2 dive[1] - 2:12 DMF[3] - 10:25, 13:10, 13:13 document[79] - 2:19, 4:6, 8:9, 8:14, 8:15, 8:17, 8:22, 9:7, 9:21, 10:5, 10:9, 10:12, 10:16, 10:17, 10:21, 11:3, 11:17, 12:12, 12:13, 12:19, 12:22, 13:2, 13:5, 13:16, 13:18, 13:21, 14:2, 14:5, 14:7, 14:13, 16:2, 16:6, 17:5, 17:18, 17:20, 17:24, 18:6, 18:9, 18:10, 18:20, 19:1, 19:9, 20:2, 20:16, 20:19, 21:2, 21:18, 22:2, 22:18, 22:21, 24:7, 28:1, 29:11, 29:12, 29:19, 29:23, 30:1, 30:5, 30:13, 30:19, 31:11, 31:13, 31:25, 33:3, 34:7, 34:8, 35:14, 35:20, 35:23, 36:10, 37:2, 37:5, 37:7, 38:7, 38:25 documents[44] - 2:12, 2:15, 3:1, 3:16, 3:23, 4:2, 4:3, 4:23, 5:4, 5:8, 5:16, 5:24, 6:13, 6:24, 6:25, 7:6, </p>
--	--

<p>8:4, 8:6, 8:11, 8:13, 10:7, 14:13, 16:6, 17:6, 19:23, 23:17, 24:2, 24:11, 24:13, 24:15, 24:16, 25:7, 25:21, 26:1, 26:2, 27:5, 27:10, 30:16, 32:24, 36:2, 39:5, 39:7, 39:9</p> <p>done [2] - 14:25, 36:13</p> <p>dose [2] - 5:18, 8:19</p> <p>double [1] - 23:13</p> <p>double-check [1] - 23:13</p> <p>dozens [3] - 11:8, 11:9</p> <p>draft [2] - 19:1, 19:9</p> <p>drafted [1] - 28:5</p> <p>drafts [1] - 28:22</p> <p>drawn [1] - 29:10</p> <p>drug [4] - 10:19, 10:23, 12:23, 13:10</p> <p>drugs [1] - 38:20</p> <p>duplicate [1] - 25:21</p> <p>duplicated [1] - 25:16</p> <p>during [3] - 9:23, 26:21, 32:6</p>	<p>14:24, 36:18</p> <p>especially [2] - 16:18, 29:3</p> <p>ESQUIRE [3] - 1:12, 1:15, 1:19</p> <p>essence [1] - 31:14</p> <p>essentially [1] - 33:20</p> <p>establishment [1] - 12:25</p> <p>ester [1] - 11:8</p> <p>et [7] - 6:18, 7:8, 7:21, 23:16, 26:22, 32:14</p> <p>evaluate [1] - 6:19</p> <p>evaluated [1] - 38:2</p> <p>evaluates [1] - 35:22</p> <p>evaluation [1] - 37:14</p> <p>evident [1] - 36:2</p> <p>evolved [1] - 27:7</p> <p>evolving [4] - 3:20, 6:23, 16:19, 27:4</p> <p>exactly [1] - 2:12</p> <p>except [1] - 34:18</p> <p>excerpt [1] - 10:19</p> <p>exhibits [1] - 7:17</p> <p>exists [1] - 14:23</p> <p>experience [1] - 6:17</p> <p>extent [6] - 7:13, 8:3, 9:22, 13:4, 18:20, 34:23</p>	<p>30:6, 39:7, 39:9</p> <p>figure [1] - 37:25</p> <p>file [5] - 7:21, 10:19, 10:23, 12:23, 13:10</p> <p>filed [2] - 7:12, 27:11</p> <p>filling [2] - 16:1, 18:21</p> <p>final [6] - 18:10, 19:11, 29:4, 29:5, 37:3, 37:5</p> <p>finalized [1] - 28:5</p> <p>finally [1] - 27:15</p> <p>findings [1] - 32:12</p> <p>fine [3] - 2:17, 5:25, 35:3</p> <p>finished [2] - 5:18, 8:19</p> <p>first [16] - 2:6, 2:18, 2:22, 2:23, 8:14, 13:11, 16:6, 17:6, 20:20, 21:2, 24:4, 25:19, 26:8, 27:23, 33:7, 37:11</p> <p>five [6] - 11:14, 16:7, 17:20, 21:18, 24:12, 34:1</p> <p>flip [1] - 17:10</p> <p>flipping [1] - 12:3</p> <p>Floor [1] - 1:20</p> <p>flowing [1] - 20:14</p> <p>follow [1] - 18:17</p> <p>following [2] - 7:23, 28:23</p> <p>FOR [1] - 1:2</p> <p>foregoing [1] - 39:19</p> <p>form [1] - 19:11</p> <p>formula [2] - 8:25, 9:8</p> <p>formulation [2] - 5:17, 8:19</p> <p>formulations [1] - 3:15</p> <p>forth [2] - 6:5, 28:4</p> <p>four [3] - 8:16, 10:17, 24:12</p> <p>fourth [2] - 3:18, 24:2</p> <p>FRANK [1] - 1:19</p> <p>Frank [1] - 12:16</p> <p>frankly [2] - 23:23, 35:11</p> <p>faith [6] - 4:16, 4:20, 10:11, 13:22, 16:2, 17:18</p> <p>fall [1] - 5:17</p> <p>falls [1] - 37:6</p> <p>far [4] - 17:15, 23:17, 26:10, 30:21</p> <p>favor [1] - 2:25</p> <p>FDA [3] - 12:25, 25:12, 37:17</p> <p>February [1] - 19:18</p> <p>few [5] - 2:22, 6:7,</p>	<p>G</p> <p>General [1] - 22:23</p> <p>generally [3] - 23:14, 25:25, 30:25</p> <p>generic [1] - 3:13</p> <p>genotoxic [1] - 23:12</p> <p>given [3] - 10:1, 12:18, 15:25</p> <p>Global [1] - 5:3</p> <p>globally [1] - 5:9</p> <p>GOLOMB [1] - 1:11</p> <p>Google [1] - 11:7</p> <p>GORDON [1] - 1:19</p> <p>GREENBERG [1] - 1:14</p> <p>Group [1] - 1:21</p> <p>guess [5] - 2:11, 14:2, 22:25, 27:11, 36:4</p> <p>guidelines [1] - 38:18</p>	<p>14:17, 15:15, 18:9</p> <p>hit [1] - 8:24</p> <p>Home [1] - 17:11</p> <p>HONIK [1] - 1:11</p> <p>Honor [30] - 2:8, 2:10, 2:13, 4:21, 5:24, 6:8, 6:15, 6:16, 7:13, 7:17, 8:2, 11:3, 11:7, 12:21, 13:15, 15:6, 18:22, 19:20, 20:4, 21:18, 27:2, 28:4, 31:25, 33:17, 35:2, 35:12, 36:10, 38:5, 39:11, 39:15</p> <p>Honor's [1] - 18:18</p> <p>HONORABLE [1] - 1:9</p> <p>hurt [2] - 5:8, 15:4</p>
	<p>F</p> <p>face [4] - 14:17, 21:2, 25:15, 35:10</p> <p>facie [1] - 13:12</p> <p>facility [1] - 15:1</p> <p>fact [16] - 6:23, 6:24, 6:25, 10:14, 11:11, 13:18, 14:16, 15:11, 15:20, 15:25, 20:12, 23:2, 26:19, 27:4, 35:19, 35:22</p> <p>factor [3] - 9:18, 10:1, 13:25</p> <p>factors [2] - 4:8, 6:21</p> <p>facts [1] - 36:20</p> <p>factual [1] - 29:10</p> <p>fairly [1] - 27:16</p> <p>faith [6] - 4:16, 4:20, 10:11, 13:22, 16:2, 17:18</p> <p>fall [1] - 5:17</p> <p>falls [1] - 37:6</p> <p>far [4] - 17:15, 23:17, 26:10, 30:21</p> <p>favor [1] - 2:25</p> <p>FDA [3] - 12:25, 25:12, 37:17</p> <p>February [1] - 19:18</p> <p>entity [3] - 14:23,</p>	<p>hand [1] - 34:9</p> <p>handwriting [1] - 27:17</p> <p>harm [22] - 4:17, 4:24, 10:12, 10:15, 11:15, 11:16, 14:22, 17:13, 20:14, 23:23, 25:17, 26:24, 27:9, 27:20, 29:23, 30:11, 30:23, 31:4, 31:6, 34:3, 34:4, 36:17</p> <p>harmed [1] - 22:1</p> <p>hazard [1] - 5:22</p> <p>head [3] - 8:24, 12:3, 28:19</p> <p>health [11] - 5:22, 10:1, 11:19, 13:24, 14:2, 19:2, 26:18, 32:1, 37:7, 37:11, 38:8</p> <p>hear [1] - 25:20</p> <p>hearing [3] - 2:13, 6:16, 30:24</p> <p>HEARING [1] - 1:6</p> <p>heart [4] - 26:13, 29:5, 30:24, 32:1</p> <p>heavily [2] - 2:25, 4:12</p> <p>helpful [1] - 23:14</p> <p>hide [1] - 23:1</p> <p>high [1] - 30:21</p> <p>high-level [1] - 30:21</p> <p>higher [1] - 38:17</p> <p>highest [1] - 29:17</p> <p>highlight [1] - 6:7</p> <p>highly [11] - 3:13, 3:14, 3:22, 4:14, 9:9, 13:14, 14:9, 14:12,</p>	<p>ICH [1] - 38:18</p> <p>identical [1] - 24:16</p> <p>identifies [1] - 9:22</p> <p>ignore [1] - 4:21</p> <p>Igor [1] - 30:3</p> <p>impact [1] - 5:4</p> <p>implicate [1] - 10:24</p> <p>implicated [1] - 3:16</p> <p>importance [2] - 10:1, 26:18</p> <p>important [6] - 15:14, 19:2, 27:8, 28:15, 38:8, 38:19</p> <p>importantly [1] - 4:19</p> <p>Impurities [1] - 22:23</p> <p>impurities [8] - 3:18, 5:20, 18:5, 22:4, 22:5, 23:12, 31:18, 37:14</p> <p>impurity [4] - 16:12, 22:6, 33:6, 33:8</p> <p>IN [1] - 1:4</p> <p>inappropriate [1] - 38:23</p> <p>Inc [2] - 1:17, 1:18</p> <p>inclination [3] - 22:17, 22:20, 23:19</p> <p>inclined [1] - 35:2</p> <p>including [3] - 5:7, 7:2, 11:14</p> <p>inconsistent [1] - 38:18</p> <p>indicate [1] - 39:8</p> <p>indicia [1] - 17:5</p> <p>individual [1] - 24:7</p> <p>Industries [1] - 1:17</p> <p>industry [7] - 3:12, 3:13, 3:19, 3:20, 14:9, 38:1, 38:18</p> <p>inferences [1] - 29:10</p>	

<p>inform [1] - 28:19 information [29] - 2:18, 3:9, 4:13, 4:14, 4:15, 8:18, 9:17, 12:24, 13:4, 14:14, 14:21, 15:4, 18:6, 18:7, 22:9, 23:16, 25:11, 25:12, 25:18, 27:19, 29:17, 30:7, 30:10, 30:20, 32:11, 34:23, 35:6, 36:3, 39:4 informative [1] - 29:24 informed [2] - 28:20, 28:21 ingredient [1] - 8:20 ingredients [2] - 9:1, 15:22 initial [3] - 8:13, 22:17, 22:20 injury [1] - 29:21 inquiry [1] - 12:3 inspection [1] - 12:25 intellectual [1] - 33:19 intend [1] - 2:19 intended [1] - 8:9 intends [1] - 36:4 interest [6] - 4:23, 13:14, 13:24, 26:18, 32:1, 38:8 interests [7] - 3:8, 5:9, 10:25, 11:19, 13:25, 29:15, 30:9 interim [1] - 37:18 internal [14] - 3:15, 3:24, 4:5, 5:21, 18:11, 25:9, 27:7, 27:19, 29:1, 29:6, 37:14, 37:16, 37:21, 39:1 internally [1] - 22:4 interrupt [1] - 2:17 inventory [1] - 34:9 involved [3] - 3:4, 3:21, 9:10 IRBESARTAN [1] - 1:5 irrelevant [3] - 15:12, 35:23, 36:10 issue [24] - 3:19, 3:22, 3:25, 5:4, 6:13, 6:23, 9:25, 11:12, 12:9, 12:12, 13:4, 13:19, 16:13, 16:14, 16:17, 16:19, 24:4, 24:20, 31:18, 32:6, 38:1, 38:2, 39:6, 39:8 issues [7] - 2:14, 2:22, 15:18, 26:13, 30:25, 31:1, 33:6</p>	<p>items [1] - 16:15 itself [6] - 4:11, 14:18, 30:19, 32:10, 32:11, 38:11 IV [1] - 1:19</p> <p style="text-align: center;">J</p> <p>JERSEY [1] - 1:2 JOHN [1] - 1:12 Joint [1] - 1:21 Judge [20] - 6:3, 6:14, 6:16, 6:22, 7:3, 7:9, 9:17, 11:6, 12:15, 13:10, 14:20, 17:10, 18:16, 18:24, 23:10, 24:23, 25:11, 25:18, 26:7, 27:11, 28:9 judge [1] - 16:24 judgment [2] - 7:20, 23:24 July [5] - 16:8, 16:12, 18:3, 37:12, 37:23 June [2] - 20:20 justify [1] - 12:4</p> <p style="text-align: center;">K</p> <p>Karen [2] - 1:22, 39:22 keep [3] - 11:1, 25:18, 36:4 keeping [2] - 3:1, 3:8 knows [3] - 6:8, 6:16, 18:22</p> <p style="text-align: center;">L</p> <p>L-I-F-S-H-I-T-Z [1] - 30:4 label [1] - 29:18 labeled [1] - 28:16 large [1] - 17:16 last [13] - 4:1, 8:12, 8:16, 10:17, 11:17, 14:7, 16:7, 17:20, 19:1, 24:4, 27:12, 30:19, 34:2 lawyer [1] - 28:24 lead [1] - 38:15 learned [2] - 25:17, 33:7 learning [1] - 16:15 least [9] - 2:20, 6:25, 9:20, 19:13, 20:17, 22:6, 28:22, 35:6, 37:17 left [2] - 34:2, 34:24 legacy [2] - 15:1, 36:18 legal [3] - 28:17, 28:18, 28:21</p>	<p>legally [1] - 29:12 legitimate [1] - 3:8 legitimately [1] - 29:15 lengthy [1] - 8:17 letter [10] - 4:9, 5:16, 8:11, 9:16, 19:1, 25:5, 26:7, 27:11, 28:9 letters [2] - 6:5, 6:6 level [2] - 29:18, 30:21 LIABILITY [1] - 1:5 liberty [1] - 25:11 life [1] - 13:19 Lifshitz [1] - 30:4 light [1] - 23:25 likely [1] - 7:18 limit [4] - 37:20, 38:17, 38:23, 39:2 limited [1] - 15:18 limits [3] - 37:18, 37:22, 38:12 line [1] - 4:3 link [1] - 23:4 list [1] - 27:12 listed [1] - 27:11 listing [1] - 34:9 literally [2] - 11:13, 16:12 literature [1] - 32:13 litigation [12] - 2:24, 3:5, 3:22, 4:7, 5:7, 5:15, 9:10, 12:17, 15:19, 21:4, 23:8, 24:20 LITIGATION [1] - 1:5 litigations [1] - 6:18 live [1] - 34:17 LLC [1] - 1:17 LLP [2] - 1:14, 1:19 look [5] - 5:10, 9:3, 23:13, 29:19, 39:7 looked [3] - 15:23, 31:2, 38:24 looks [1] - 27:7 LOSARTAN [1] - 1:4 Lowe's [1] - 17:11 Ltd [1] - 1:17</p> <p style="text-align: center;">M</p> <p>mail [1] - 30:2 maintain [2] - 10:9, 13:5 Malta [1] - 15:1 management [1] - 31:14 Management [1] - 5:3 manifest [1] - 35:8 manufacturers [1] -</p>	<p>14:10 manufacturing [3] - 9:24, 15:11, 15:12 March [2] - 22:23, 27:18 mark [1] - 28:21 marked [4] - 3:1, 3:6, 8:6, 23:1 Market [1] - 1:12 market [3] - 14:25, 15:5, 15:24, 16:1, 16:16, 16:21, 16:25, 17:1, 17:16, 17:20, 18:1, 18:16, 18:24, 19:20, 20:1, 20:4, 20:25, 21:17, 22:3, 22:25, 23:10, 24:9, 25:22, 25:25, 27:2, 28:3, 29:9, 30:6, 30:18, 31:13, 31:24, 32:17, 33:5, 33:17, 34:12, 34:17, 34:21, 35:2, 35:19, 36:9, 37:13, 38:5, 39:11, 39:12 mute [1] - 2:4 Mylan [9] - 1:21, 5:13, 11:16, 12:10, 12:11, 12:16, 13:10, 13:14, 24:18 Mylan's [4] - 10:25, 12:23, 13:4, 33:8</p> <p style="text-align: center;">N</p> <p>nail [1] - 8:24 names [2] - 9:24, 11:14 nature [2] - 3:12, 10:24 NDMA [5] - 16:9, 17:1, 37:20, 38:7, 39:2 nearly [1] - 14:21 necessarily [2] - 13:3, 19:25 need [2] - 2:15, 25:13 needs [1] - 14:1 negate [2] - 6:23, 14:16 negotiated [1] - 4:12 negotiations [1] - 12:20 NEW [1] - 1:2 new [5] - 3:19, 3:25, 6:23, 26:5, 37:25 next [11] - 10:17, 14:5, 17:20, 20:19, 22:21, 27:13, 27:14, 29:20, 30:1, 32:24 nine [5] - 15:3, 24:12, 24:15, 36:13, 36:18 nitrosamine [10] - 3:18, 5:20, 6:22, 13:19, 16:12, 18:5, 26:13, 31:18, 33:6, 37:14 nitrosamines [2] - 7:2, 17:1 none [1] - 3:3 note [3] - 6:22, 10:5, 37:10 nothing [12] - 3:6,</p>
---	---	---	--

<p>11:10, 20:7, 21:4, 23:14, 23:15, 29:20, 31:3, 36:11, 38:12, 39:11, 39:12 notice [2] - 34:23, 34:24 notices [1] - 35:5 November [2] - 14:6, 33:9 Nudelman [1] - 38:16 NUDELMAN [1] - 38:16 number [6] - 15:2, 16:8, 22:22, 26:7, 26:9, 27:12 NUMBER [1] - 1:4 Number [2] - 6:8, 23:20 numbering [1] - 24:5 numbers [4] - 8:12, 10:17, 24:14, 24:17 numerous [1] - 5:7</p>	<p>order [10] - 4:11, 5:18, 6:10, 8:10, 14:6, 14:22, 14:23, 15:10, 35:9 order's [1] - 10:6 orders [2] - 6:9, 6:20 organization [1] - 28:20 otherwise [4] - 2:5, 3:4, 6:17, 38:13 overall [1] - 15:19 overarching [2] - 2:14, 2:22 overcome [1] - 4:25 own [1] - 38:13 Oxford [1] - 1:20</p>	<p>1:13, 1:16 physical [1] - 26:20 pictures [1] - 11:9 piece [1] - 8:3 PIETRAGALLO [1] - 1:19 Pittsburgh [1] - 1:20 place [3] - 6:10, 13:11, 16:4 Plaintiff [1] - 1:13 plaintiffs [12] - 3:2, 3:16, 3:24, 4:4, 4:21, 6:4, 12:20, 25:5, 28:10, 28:12, 39:12 plaintiffs' [4] - 4:1, 4:9, 22:25, 28:9 plants [1] - 26:22 pleadings [2] - 7:12, 7:19 plus [1] - 23:10 point [4] - 13:6, 26:9, 26:20, 28:20 points [1] - 6:7 portion [1] - 12:23 position [2] - 12:19, 12:21 positions [1] - 6:5 potential [2] - 4:16, 33:8 presented [1] - 7:7 presumption [1] - 5:1 pretty [2] - 2:23, 5:23 previously [1] - 4:22 price [2] - 3:14, 14:17 prices [2] - 14:10, 35:10 pricing [2] - 14:14, 15:4 prima [1] - 13:12 primary [1] - 4:1 privacy [1] - 4:23 privileged [4] - 28:16, 28:22, 29:12, 29:13 proceed [4] - 2:4, 5:25, 14:5, 35:12 proceeding [1] - 16:1 proceedings [1] - 39:20 Proceedings [1] - 1:24 process [4] - 9:24, 25:9, 28:6, 28:18 processes [19] - 3:10, 3:15, 3:25, 4:5, 9:2, 9:4, 9:13, 18:14, 19:21, 27:3, 27:4, 27:7, 27:20, 29:6, 30:7, 33:18, 35:24, 37:17, 37:21 produced [3] - 1:24,</p>	<p>13:12, 14:14 producing [3] - 4:16, 4:19, 4:24 Product [1] - 34:20 product [4] - 9:1, 34:9, 36:21, 38:13 PRODUCTS [1] - 1:5 products [5] - 9:6, 9:19, 15:12, 15:20, 26:11 pronouncing [1] - 7:25 properly [1] - 22:5 proposed [1] - 37:20 proprietary [16] - 3:23, 3:25, 4:14, 9:9, 9:13, 11:11, 18:9, 20:7, 20:14, 23:14, 29:16, 30:20, 33:18, 38:3, 38:10, 39:3 protect [1] - 3:8 protective [5] - 4:10, 4:11, 6:10, 6:20, 10:6 provide [2] - 8:18, 17:17 provisions [1] - 10:7 public [21] - 5:1, 7:5, 7:14, 9:25, 11:19, 13:1, 13:24, 14:1, 18:6, 18:7, 19:2, 22:8, 23:22, 26:17, 32:1, 32:13, 32:14, 35:7, 36:4, 38:8, 38:19 public's [1] - 12:5 publication [1] - 5:8 publicly [3] - 7:1, 14:11, 23:4 published [1] - 23:21 pull [5] - 8:15, 10:18, 17:21, 27:24, 37:7 pulling [1] - 10:18 purchase [6] - 5:18, 14:6, 14:22, 15:10, 35:9 purchased [1] - 14:16 purchases [1] - 15:15 purchasing [2] - 15:21, 15:22 pushed [1] - 28:25 pushing [1] - 38:23 put [3] - 16:22, 18:16, 23:8 putting [1] - 36:20</p>	<p>30:25 quantities [2] - 14:16, 15:13 quantity [1] - 35:10 questioned [1] - 28:11 quite [3] - 6:5, 14:20, 26:19 quote [1] - 13:13</p>
<p>O</p> <p>older [1] - 27:5 One [1] - 1:20 one [24] - 4:1, 4:4, 5:17, 6:25, 10:2, 11:4, 11:17, 12:6, 12:19, 13:3, 13:20, 14:12, 15:13, 23:6, 23:10, 23:11, 23:25, 24:12, 24:21, 25:19, 30:19, 30:22, 38:20 ongoing [1] - 5:6 open [2] - 13:13, 17:22 operates [1] - 15:1 opportunity [1] - 12:18 opposite [1] - 23:2 oppositions [1] - 7:21</p>	<p>party [5] - 4:16, 4:25, 10:25, 25:11, 30:9 patent [1] - 9:10 patents [2] - 9:12, 11:11 PC [1] - 1:11 Pennsylvania [2] - 1:13, 1:20 people [3] - 28:19, 28:21, 37:24 per [1] - 35:6 permission [2] - 25:14, 36:2 perspective [1] - 38:9 Pharma [1] - 1:18 pharmaceutical [5] - 3:12, 3:13, 3:19, 8:20, 15:22 Pharmaceutical [1] - 1:17 Pharmaceuticals [1] - 1:17 Philadelphia [2] -</p>	<p>party [5] - 4:16, 4:25, 10:25, 25:11, 30:9 patent [1] - 9:10 patents [2] - 9:12, 11:11 PC [1] - 1:11 Pennsylvania [2] - 1:13, 1:20 people [3] - 28:19, 28:21, 37:24 per [1] - 35:6 permission [2] - 25:14, 36:2 perspective [1] - 38:9 Pharma [1] - 1:18 pharmaceutical [5] - 3:12, 3:13, 3:19, 8:20, 15:22 Pharmaceutical [1] - 1:17 Pharmaceuticals [1] - 1:17 Philadelphia [2] -</p>	<p>party [5] - 4:16, 4:25, 10:25, 25:11, 30:9 patent [1] - 9:10 patents [2] - 9:12, 11:11 PC [1] - 1:11 Pennsylvania [2] - 1:13, 1:20 people [3] - 28:19, 28:21, 37:24 per [1] - 35:6 permission [2] - 25:14, 36:2 perspective [1] - 38:9 Pharma [1] - 1:18 pharmaceutical [5] - 3:12, 3:13, 3:19, 8:20, 15:22 Pharmaceutical [1] - 1:17 Pharmaceuticals [1] - 1:17 Philadelphia [2] -</p>	

<i>released</i> [1] - 24:22 <i>relevant</i> [2] - 15:15, 36:19 <i>relying</i> [1] - 17:15 <i>remain</i> [24] - 2:16, 9:14, 10:13, 10:16, 12:13, 12:22, 13:6, 13:23, 14:3, 16:4, 17:19, 19:12, 20:17, 22:24, 24:11, 27:21, 27:23, 28:1, 30:5, 31:11, 33:3, 35:15 <i>remotely</i> [1] - 36:14 <i>removed</i> [1] - 15:12 <i>report</i> [7] - 24:4, 25:6, 28:15, 30:8, 31:2, 32:10, 32:11 <i>Reporter</i> [1] - 1:22 <i>Reporter/Transcriber</i> [1] - 39:22 <i>reports</i> [14] - 5:20, 5:21, 12:25, 24:3, 24:8, 24:18, 26:10, 27:10, 27:15, 28:3, 28:5, 28:25, 29:2, 30:14 <i>represent</i> [1] - 12:16 <i>representation</i> [1] - 4:24 <i>request</i> [1] - 10:8 <i>respect</i> [7] - 8:18, 8:21, 10:7, 22:7, 25:5, 28:16, 30:11 <i>respectfully</i> [1] - 12:2 <i>respond</i> [2] - 6:6, 15:7 <i>RESPONSE</i> [1] - 39:15 <i>rest</i> [1] - 35:14 <i>result</i> [7] - 11:15, 19:25, 29:20, 31:4, 34:3, 34:4, 36:17 <i>results</i> [5] - 17:5, 20:8, 23:15, 38:11, 38:13 <i>reveal</i> [5] - 15:19, 18:13, 27:19, 36:3, 39:1 <i>revealed</i> [2] - 15:16, 16:13 <i>revealing</i> [3] - 23:6, 27:8, 33:18 <i>reveals</i> [3] - 35:23, 37:20, 39:3 <i>revelation</i> [1] - 38:6 <i>review</i> [1] - 29:19 <i>reviewed</i> [2] - 10:4, 28:5 <i>reviews</i> [1] - 25:6 <i>rights</i> [1] - 6:9	<i>rigor</i> [1] - 33:19 <i>risk</i> [1] - 5:21 RMR [1] - 39:22 <i>routes</i> [1] - 10:2 Rubenstein [25] - 2:11, 6:7, 7:24, 8:22, 10:20, 12:8, 12:15, 12:17, 14:8, 16:10, 18:1, 19:19, 20:22, 22:1, 22:24, 25:20, 26:5, 27:1, 28:2, 31:12, 32:16, 33:4, 34:5, 35:18, 37:9 RUBENSTEIN [34] - 1:15, 2:8, 2:10, 2:21, 7:23, 8:1, 8:23, 10:22, 12:10, 14:9, 15:6, 15:9, 16:11, 18:3, 18:13, 19:20, 20:1, 20:25, 22:3, 22:25, 24:9, 25:22, 27:2, 28:3, 30:6, 31:13, 32:17, 33:5, 34:12, 34:17, 34:21, 35:19, 37:13, 39:11 <i>rule</i> [1] - 4:3 <i>ruled</i> [1] - 18:20 <i>ruling</i> [1] - 4:21 <i>rulings</i> [1] - 18:18 <i>run</i> [1] - 4:5	<i>seem</i> [1] - 8:18 <i>sell</i> [1] - 36:21 <i>sellers</i> [1] - 38:20 <i>selling</i> [2] - 9:20, 33:21 <i>sells</i> [1] - 5:11 <i>senior</i> [1] - 31:14 <i>Senior</i> [1] - 5:3 <i>sense</i> [1] - 24:9 <i>sensitive</i> [8] - 3:9, 3:23, 4:15, 13:14, 14:12, 20:13, 30:20, 38:10 <i>sensitivity</i> [3] - 23:18, 29:11 <i>sentences</i> [1] - 29:10 SEPTEMBER [1] - 2:2 September [3] - 1:7, 30:2, 39:24 <i>sequence</i> [1] - 24:5 <i>set</i> [1] - 6:5 <i>seven</i> [3] - 23:10, 23:20, 24:12 <i>seven-plus</i> [1] - 23:10 <i>several</i> [3] - 8:12, 24:4, 27:12 <i>shall</i> [4] - 17:19, 19:12, 20:17, 27:21 <i>share</i> [3] - 9:9, 25:12 <i>shared</i> [2] - 13:18, 18:11 <i>shipped</i> [1] - 14:25 Shop [1] - 17:12 Shop-Vac [1] - 17:12 <i>show</i> [8] - 3:24, 6:11, 11:11, 14:20, 16:24, 18:16, 18:24, 20:4, 21:17, 23:10, 25:25, 29:9, 30:18, 31:24, 33:17, 35:2, 36:9, 38:5, 39:12 showing [12] - 12:6, 15:3, 15:14, 16:16, 18:10, 20:7, 20:8, 36:12, 36:16, 37:16, 38:1, 38:15 <i>shown</i> [6] - 10:11, 13:22, 14:1, 14:21, 29:14, 36:18 <i>shows</i> [16] - 8:24, 8:25, 9:8, 9:12, 11:6, 13:12, 14:16, 15:13, 19:21, 22:3, 22:6, 23:2, 27:6, 28:6, 31:13, 35:21 <i>significant</i> [5] - 11:15, 11:16, 16:22, 17:12, 29:21 <i>similar</i> [3] - 18:3, 28:3, 30:18 <i>simply</i> [1] - 3:7, 4:6, 14:20, 23:16, 29:20, 31:3, 34:8, 35:8, 35:11 <i>stick</i> [1] - 27:18 <i>still</i> [6] - 5:11, 5:12,	<i>single</i> [1] - 3:20 <i>site</i> [2] - 15:11, 15:13 <i>situation</i> [2] - 2:23, 3:3 <i>six</i> [2] - 5:17, 24:12 <i>slippery</i> [1] - 4:7 <i>slope</i> [1] - 4:7 <i>sold</i> [1] - 9:19 <i>solvent</i> [1] - 11:14 <i>solvents</i> [3] - 9:23, 9:25, 10:1 <i>sorry</i> [2] - 4:15, 27:2 <i>sort</i> [3] - 9:4, 26:17, 37:24 <i>space</i> [1] - 17:23 <i>speaking</i> [2] - 2:5, 6:3 <i>speaks</i> [1] - 14:18 SPECIAL [1] - 1:9 <i>specific</i> [4] - 15:3, 23:15, 25:13, 36:15 <i>specifically</i> [4] - 8:6, 25:5, 26:12, 26:23 <i>specifics</i> [1] - 31:1 <i>stage</i> [1] - 7:11 <i>stale</i> [2] - 14:21, 26:19 <i>staleness</i> [1] - 9:17 <i>stand</i> [1] - 23:25 <i>standard</i> [4] - 7:15, 17:14, 38:18 <i>standards</i> [1] - 4:20 STANOCHE [24] - 1:12, 6:3, 7:9, 9:16, 11:3, 11:6, 11:20, 13:9, 14:20, 16:24, 18:16, 18:24, 20:4, 21:17, 23:10, 25:25, 29:9, 30:18, 31:24, 33:17, 35:2, 36:9, 38:5, 39:12 Stanoch [25] - 6:2, 8:7, 9:15, 11:2, 13:8, 13:17, 14:19, 16:23, 18:15, 20:2, 21:16, 23:9, 25:20, 25:24, 26:25, 29:8, 29:22, 30:17, 31:5, 31:23, 33:16, 34:6, 35:1, 36:8, 38:4 <i>start</i> [1] - 7:5 <i>state</i> [1] - 18:18 <i>statements</i> [2] - 30:21, 36:16 STATES [1] - 1:2 States [3] - 5:12, 9:19, 9:21 <i>staying</i> [1] - 31:2 <i>simply</i> [1] - 3:7, 4:6, 14:20, 23:16, 29:20, 31:3, 34:8, 35:8, 35:11 <i>stick</i> [1] - 27:18 <i>still</i> [6] - 5:11, 5:12,
			T <i>tackling</i> [3] - 3:22, 3:25, 16:17 <i>technical</i> [1] - 2:3 <i>teed</i> [1] - 17:22 <i>ten</i> [6] - 10:14, 14:21, 15:4, 26:21, 31:4, 31:7 <i>term</i> [1] - 4:13 <i>terms</i> [9] - 23:3, 23:18, 26:17, 29:18, 30:9, 32:11, 32:13, 35:7, 36:14 <i>test</i> [6] - 5:19, 10:6,

<p>16:21, 17:5, 22:6, 23:15</p> <p>tested [1] - 38:13</p> <p>testified [1] - 28:18</p> <p>testing [13] - 5:19, 16:6, 16:9, 16:17, 16:25, 19:21, 20:8, 23:3, 23:5, 23:15, 38:10, 38:11</p> <p>tests [3] - 19:21, 22:4</p> <p>Teva [72] - 1:17, 1:17, 2:7, 2:11, 3:6, 3:7, 5:5, 5:11, 5:13, 6:11, 8:4, 9:9, 9:10, 9:20, 10:8, 10:11, 10:25, 13:11, 13:12, 13:18, 13:22, 14:21, 14:24, 15:3, 15:10, 15:15, 15:20, 15:21, 16:1, 16:13, 16:24, 17:13, 17:18, 18:8, 20:7, 20:14, 22:1, 22:3, 22:7, 23:2, 23:6, 23:11, 23:24, 24:19, 25:7, 25:11, 25:17, 25:18, 26:1, 26:11, 26:20, 27:20, 28:6, 29:4, 29:14, 29:21, 29:23, 30:10, 30:11, 31:4, 33:19, 34:4, 35:7, 35:21, 35:22, 36:3, 36:19, 37:18, 38:1, 38:12, 38:13, 38:25</p> <p>Teva's [26] - 2:24, 3:24, 4:5, 5:3, 5:5, 8:10, 12:3, 12:6, 16:21, 19:21, 20:7, 20:8, 23:24, 25:9, 27:3, 27:6, 30:7, 31:14, 33:8, 34:22, 34:24, 35:5, 37:14, 37:16, 37:20, 38:15</p> <p>THE [2] - 1:2, 1:9</p> <p>The Court [56] - 2:3, 2:9, 2:17, 6:1, 7:4, 7:13, 7:22, 7:24, 8:8, 9:15, 10:4, 11:2, 11:5, 11:18, 12:8, 13:7, 13:21, 14:19, 15:8, 15:25, 16:23, 17:14, 18:12, 18:15, 18:23, 19:9, 19:24, 20:2, 20:16, 21:16, 22:1, 22:8, 22:17, 23:9, 23:19, 25:19, 25:23, 26:25, 27:10, 29:7, 29:22, 30:17, 31:5, 31:23, 32:15, 33:16, 34:5, 34:15, 34:19, 35:1, 35:13</p>	<p>36:8, 37:1, 38:4, 38:24, 39:14</p> <p>themselves [1] - 27:16</p> <p>therefore [3] - 24:1, 29:24, 31:7</p> <p>they've [2] - 17:1, 36:18</p> <p>thinking [1] - 31:14</p> <p>thinks [1] - 27:8</p> <p>third [8] - 3:12, 4:23, 4:25, 5:5, 10:25, 16:5, 25:11, 30:9</p> <p>third-party [3] - 10:25, 25:11, 30:9</p> <p>THOMAS [1] - 1:9</p> <p>thoughts [1] - 37:17</p> <p>thread [3] - 20:19, 21:5, 27:25</p> <p>three [4] - 24:12, 26:8, 31:25, 38:9</p> <p>throughout [3] - 18:9, 18:17, 28:17</p> <p>throughs [1] - 26:21</p> <p>today [20] - 6:4, 7:16, 11:15, 13:16, 15:3, 15:4, 17:1, 17:13, 18:17, 18:20, 20:15, 23:18, 26:23, 26:24, 29:11, 29:21, 31:4, 36:15, 36:19, 39:10</p> <p>Tony [1] - 5:2</p> <p>tool [1] - 20:13</p> <p>top [6] - 20:20, 21:5, 26:17, 27:24, 30:2, 37:11</p> <p>touchstone [1] - 35:4</p> <p>Toxic [1] - 22:23</p> <p>toxic [1] - 38:22</p> <p>toxicologist [3] - 38:15, 38:16, 38:22</p> <p>toxicology [1] - 37:15</p> <p>trade [1] - 4:14</p> <p>transcript [3] - 1:24, 39:6, 39:19</p> <p>transcription [1] - 1:24</p> <p>TRAURIG [1] - 1:14</p> <p>treating [1] - 16:20</p> <p>trouble [1] - 20:21</p> <p>true [1] - 23:25</p> <p>trump [1] - 6:9</p> <p>try [1] - 9:11</p> <p>trying [3] - 3:8, 3:24, 37:25</p> <p>two [9] - 11:6, 17:6, 24:12, 24:16, 24:19, 24:20, 24:22, 28:11, 35:6</p> <p>type [3] - 12:24, 25:18, 36:3</p>	<p>types [1] - 9:24</p> <p style="text-align: center;">U</p> <p>U.S. [4] - 14:25, 15:5, 15:24, 36:21</p> <p>ultimate [1] - 32:12</p> <p>ultimately [1] - 30:8</p> <p>unclear [1] - 26:23</p> <p>uncovered [1] - 16:13</p> <p>under [5] - 6:19, 27:12, 36:15, 37:2, 37:6</p> <p>understood [1] - 20:1</p> <p>unique [1] - 2:23</p> <p>UNITED [1] - 1:2</p> <p>United [3] - 5:12, 9:19, 9:21</p> <p>unless [2] - 25:12, 27:17</p> <p>unlike [1] - 32:15</p> <p>unredacted [1] - 34:25</p> <p>unseal [6] - 11:19, 22:17, 22:21, 23:20, 35:3, 35:14</p> <p>unsealed [9] - 22:2, 24:1, 29:25, 31:8, 34:8, 34:11, 37:4, 39:1, 39:4</p> <p>unsealing [1] - 31:6</p> <p>up [14] - 7:23, 8:15, 10:18, 12:13, 17:21, 17:22, 27:24, 29:5, 34:1, 37:8, 37:15, 37:17, 37:21</p> <p>USA [1] - 1:17</p>	<p>versa [1] - 14:11</p> <p>versus [2] - 7:14, 12:4</p> <p>VIA [1] - 2:1</p> <p>Via [1] - 1:6</p> <p>vice [1] - 14:11</p> <p>videoconference [1] - 1:6</p> <p>VIDEOCONFERENCE E [1] - 2:1</p> <p>view [1] - 13:22</p> <p>views [2] - 11:14, 37:19</p> <p>vintage [1] - 31:24</p> <p>virtue [1] - 26:2</p> <p style="text-align: center;">W</p> <p>wait [1] - 39:6</p> <p>waive [1] - 26:1</p> <p>waiving [1] - 18:19</p> <p>walk [1] - 26:21</p> <p>walk-throughs [1] - 26:21</p> <p>wants [2] - 2:13, 6:15</p> <p>water [1] - 11:14</p> <p>ways [2] - 9:5, 23:5</p> <p>weeks [1] - 16:12</p> <p>weigh [3] - 2:25, 6:21, 27:5</p> <p>weighs [1] - 10:3</p> <p>whole [2] - 24:6, 37:4</p> <p>windows [1] - 17:22</p> <p>witnesses [1] - 13:3</p> <p>world [2] - 5:7, 33:20</p> <p>writing [1] - 22:19</p> <p>written [2] - 39:8, 39:9</p>	<p style="text-align: center;">Y</p> <p>year [4] - 14:21, 15:4, 31:4, 35:23</p> <p>years [17] - 6:24, 6:25, 10:14, 14:25, 15:2, 21:18, 23:10, 23:20, 26:9, 26:21, 31:7, 31:25, 34:1, 36:13, 36:19, 38:9</p> <p style="text-align: center;">Z</p> <p>ZHP [8] - 5:12, 14:24, 15:21, 24:19, 28:14, 30:22, 30:24, 33:21</p> <p>ZHP's [1] - 4:22</p> <p>Zoom [1] - 1:6</p> <p>ZOOM [1] - 2:1</p>
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